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**UNITED STATES DISTRICT COURT
DISTRICT OF OREGON**

THE CHURCH OF THE HOLY LIGHT)
OF THE QUEEN, a/k/a The Santo Daime)
Church, *et al.*,)
Plaintiffs,)
v.)
MICHAEL B. MUKASEY, *et al.*,)
Defendants.)
_____)

CIV. NO. 08-3095-PA

**WITNESS STATEMENT OF
ALEXANDER WALKER,
M.D., Dr.P.H.**

REPORT OF ALEXANDER M. WALKER, MD, DrPH

December 4, 2008

Background

1. My name is Alexander M. Walker. I am Adjunct Professor of Epidemiology at the Harvard School of Public Health, and I am a Principal in the firm World Health Information Science Consultants, LLC. I teach and conduct epidemiologic research. World Health Information Science Consultants, LLC has been hired by the Department of Justice at the rate of \$500 per hour of my time to provide testimony in this case.

2. I earned doctorates in Medicine (1974) and Epidemiology (1980) from Harvard University, where I joined the faculty of the School of Public Health in 1979, eventually rising to the positions of Professor of Epidemiology and Chair of the Department of Epidemiology. I hold an undergraduate degree in Biochemistry and a Master's of Public Health degree, both from Harvard as well. My curriculum vitae and a full listing of my scientific publications are attached.

3. Essentially my entire research career has been devoted to the epidemiologic study of the safety of drugs, medical devices and vaccines. Studies in which I have played a leading role over the past 30 years include nearly the whole range of modern therapeutics. I have published as principal author or coauthor, over 275 research papers, editorials, commentaries, book chapters and reviews. I teach courses in epidemiologic methods and in the science of pharmacoepidemiology (the epidemiologic study of drug effects) to graduate students at Harvard. The topics of my courses include specific

instruction on the proper conduct of each of the kinds of research that I will discuss below. I sit on graduate student thesis research committees at Harvard.

4. I have served as consulting statistician to the *New England Journal of Medicine* and as Contributing Editor to *The Lancet*. I am a member of the Editorial Board of the journal *Pharmacoepidemiology and Drug Safety*. My responsibilities at these medical journals over the years have involved the detailed analysis of many hundreds of research papers submitted for publication, both as part of the peer review process and at a stage when they had passed peer review. Serving in these functions, I have acquired substantial expertise in the evaluation of epidemiologic research.

5. I have not participated in any court proceedings in the last four years. On August 31, 2001, I submitted an expert report in response to declarations of Charles Grob (see below) and in December 2001, I presented expert testimony in *O Centro Esperita Beneficiente União do Vegetal v. Ashcroft* concerning the safety of ayahuasca tea for human consumption.

6. In addition to explaining the materials I reviewed and the conclusions I reached in *O Centro Esperita*, I have been asked to evaluate the Amended Expert Witness Statement of Dr. John H. Halpern and a 2008 study he published concerning the safety of ayahuasca. I have also been asked to evaluate a secondary literature review published by Robert S. Gable, to the extent that it provides further information on the safety of ayahuasca consumptions and an Amended Expert Witness Statement of Nicholas V. Cozzi, PhD, concerning the safety of ayahuasca. To this end, I have reviewed the following documents: Declaration of Charles S. Grob, M.D., marked as "Plaintiff's Exhibit F"; Second Declaration of Charles S. Grob, M.D., marked "Exhibit V"; Report of

Sander G. Genser, M.D., M.P.H., marked as "Defendants Exhibit 22"; Amended Expert Witness Statement of Dr. John H. Halpern, November 5, 2008; "Human Psychopharmacology of Hoasca, a Plant Hallucinogen Used in a Ritual Context in Brazil" by Charles S. Grob and others, published in 1996 in the *Journal of Nervous and Mental Disorders*, Vol. 184, pp. 86-94; "The Scientific Investigation of Ayahuasca: A Review of Past and Current Research" by Dennis J. McKenna, Ph.D., J. C. Callaway, Ph.D. and Charles S. Grob, M.D. published in 1998 in *The Heffter Review of Psychedelic Research* Vol. I, pp. 65-77; "Ayahuasca Preparations and Serotonin Reuptake Inhibitors," by James C. Callaway and Charles S. Grob, published in 1998 in the *Journal of Psychoactive Drugs*, Vol. 30, pp 367-369; "Platelet Serotonin Uptake Sites Increased in Drinkers of *Ayahuasca*," by James C. Callaway and others, published in 1994 in *Psychopharmacology*, Vol. 166, pp. 385-387; "Evidence of health and safety in American members of a religion who use a hallucinogenic sacrament" by John H. Halpern, Andrea R. Sherwood, Torsten Passle, Kimberly C. Blackwell, and A. James Rutenber, published in 2008 in the *Medical Science Monitor*, Vol. 14, pp. SR15-22; "Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids" by Robert S. Gable, published in 2007 in *Addiction*, Vol. 102, pp. 24-34; Excerpts from the Declaration of Jonathan Goldman (October 3, 2008); Declaration of Nicholas V. Cozzi, Ph.D. dated June 5, 2008; Witness Statement of Nicholas V. Cozzi, no date, two pages long, signed /s/ Roy S. Haber; Report of Drug Property Collected, Purchased or Seized, dated 5/20/99 and labelled "Plaintiff's Exhibit 4".

Summary

7. Based on my review of the above materials and my extensive training in and knowledge of the fields of epidemiology, biostatistics and drug safety evaluation, it is my opinion that the research on which Drs. Halpern, Cozzi and Grob base their conclusions is inadequate to support any meaningful statement about the safety of consumption of ayahuasca. The report published by Dr. Halpern does not meet even minimal criteria for scientific rigor. Limited data adduced by Mr. Gable suggest psychological harm.

Analysis

A. Principles

8. Studies of the effects of drugs on humans encompass both experimental and nonexperimental (observational) research. An investigation of a causal effect is tantamount to asking the hypothetical question, "If we could compare the health of a person who has taken the drug to what his or her health would have been had he or she not taken the drug, how would those two states of health differ?" The difference between the observed state and the state that would have existed in the absence of taking the drug is the causal effect of the drug. This formulation of the causal effect is theoretical because one of the two states of health is "counterfactual": it is not possible for a person at the same time to both have and have not taken the drug. The theoretical formulation does however set a criterion against which to compare feasible studies.

9. The practical method for assessing drug effects that comes closest to the above hypothetical is the double-blind randomized controlled trial. In such a trial, a suitably large number of patients is assembled, and some are chosen at random to receive the drug

being tested, and the remainder receives an inactive agent, called a placebo. Although the individuals receiving the active drug and the placebo are different persons, the two groups can be expected to have similar characteristics overall, by virtue of the random selection of the group members from the common pool of study candidates. The pretreatment differences between the groups are only those that have arisen by chance, and the role of chance can be reduced to any desired small level by selecting sufficiently large comparison groups. The exact number of subjects that need to be enrolled depends on the variability of the health outcomes to be measured and the size of the health effect that the investigator wishes to identify. Typically studies relied upon for new drug approvals in the United States include many thousands of patients, though occasionally they may involve only several hundred.

10. Neither the study subjects nor the persons caring for them are told whether they are given the active drug or a placebo. This withholding of information from both the study subjects and the persons who have contact with them is the meaning of the term "double blind." The purpose of blinding is to prevent the situation in which knowledge of treatment leads to hopes, fears or expectations that can affect the comparison between active drug and placebo. The potential for such distortion has been noted even when standardized measurement tools are used to evaluate subjects, and is particularly present when the evaluation relies on self-reporting or other subjective measures.

11. When it is not practical or ethical to conduct a double-blind randomized controlled trial, investigators may undertake a prospective, comparative cohort study. A cohort is a group of people followed forward from a definite point in time, and a prospective comparative cohort study sets the evolving health experience of two groups

against one another. In the study of drugs, a comparative cohort study differs from a randomized controlled trial in that assignment to active drug and comparison group comes not from the research investigators, but instead from forces outside the study, such as social, economic, historical and medical circumstances that influence the patients' and doctors' choices. Because the research involves no clinical intervention, it is classed as an "observational" study, whereas the controlled trial is properly an experiment.

Investigators who embark on observational studies employ a number of strategies for assuring that the comparison between cohorts is likely to correspond to the average causal effect of the drug in individuals. For instance, they may choose subjects who were very similar to one another prior to any use of the drug. They may arrange that any person involved in assessment of health states is unaware of the treatment status of the study subjects. They employ standardized measurement tools that reduce the room for interpretation that could be influenced by subjects' beliefs about their treatments.

12. Retrospective comparative cohort studies – another class of observational study – share many features with their prospective counterparts, except that investigators quantify drug exposure and health status after the fact. There are still compared groups, selected by the investigator to be as similar as possible, but the drug exposure that characterizes each group has occurred in the past, sometimes continually up to the present. The study, mimicking the prospective comparative cohort study, seeks out everyone who belonged or belongs to each group, and identifies the health of members of each group as it has evolved since joining the group. The researcher will still withhold information on subsequent health status from whoever assesses subjects' historical exposure to the study drug, and will similarly withhold knowledge about drug exposure

from whoever makes health assessments in the study subjects. The study subjects themselves will be provided with as little information as possible about the purpose and details of the study, to the limit of what is consistent with ethical research practice.

B. Declaration of Dr. John H. Halpern and His 2008 Study

13. Dr. Halpern's research, summarized on page 3 of his report, and described in more detail in his publication the Medical Science Monitor, involved interviews with 32 (out of 40) current members of an American religious group drinking ayahuasca tea, members of the Santo Daime church. In addition to the eight current members who were unavailable for interview, Dr. Halpern reports that his team did not contact approximately 110 former members of the church. The interview involved open-ended questions about advantages and disadvantages of church membership and formal evaluations for the presence of current and past psychopathology. The researchers found that the interviewees were largely happy with the church and its services, that they had experienced high levels of psychiatric disorders, drug and alcohol abuse prior to joining the church, and that as current members they were little burdened by their prior psychiatric and behavioral disorders. Test scores on many measures of psychiatric functioning were significantly better for the participants than national norms.

14. As a basis for establishing the safety of regular, ritual ayahuasca use, Dr. Halpern's work suffered from all the defects of the Hoasca Project's work a decade earlier, and added further defects in design.

15. Whereas the Hoasca Project at least sought out a comparator group that was demographically similar to the Ayahuasca users, Halpern used instead only an implied

comparator group of "national norms" for the standardized tests administered. The subjects who are the basis for these national figures are almost certainly far removed socially and probably psychologically from the regular church attendees selected for the study.

16. Church members who suffered harm from ayahuasca in the past would have been omitted from Dr. Halpern's interviews. The former members of Santo Daime not included in the study outnumbered study participants by a factor of more than three to one. Had regular ayahuasca consumption had deleterious physical or psychological effects, it might reasonably have led members to part ways with the church, and those individuals were omitted from the study. Thus, an interview study of current, longtime members necessarily omits precisely those people most likely to have suffered harm.

17. Irregular attendees at the ceremonies were omitted. In restricting the interviews to regular attendees, Dr. Halpern chose the group of ayahuasca recipients with the strongest social and psychological supports through the church. Irregular attendees, deprived of these advantages of church membership, might well be at higher risk, and should have been included in the research.

18. Both subjects and researchers were aware of the subject's ayahuasca use and Dr. Halpern relates that he had previously taken highly public positions in defense of the tea's safety. According to Jonathan Goldman, counsel for the Santo Daime Church, knowing of Dr. Halpern's position, had recruited him to perform the research. Unblinded interviews of religious adherents by public advocates for their cause do not meet any standard of objective scientific evaluation.

19. There is no before-and-after comparison of the effect of ayahuasca. The historical information on the subject's well-being did not constitute true baseline information for a before-and-after comparison because it was obtained only long after the fact. We do not know well whether any of the characteristics of the Santo Daime members uncovered in the standardized tests represent a change from their condition prior to first using ayahuasca.

20. As in the Hoasca Project's work with the members of the UDV in Brazil, Dr. Halpern's assessments were based on a small number of persons, with resulting statistically unstable estimates of group average values and a very small probability of detecting occasional individuals with serious negative experiences.

21. I have therefore identified at least six defects in Dr. Halpern's research.

a. Non-comparable comparators. "National norms" would not be expected to represent a valid comparison measure for the test results of the Santo Daime church members.

b. Excluding those most likely to manifest an ill effect. Omission of earlier church leavers through restriction of interviews to current members assured that persons who had suffered serious harm would be outside the study.

c. Including only those with strongest institutional support from the Santo Daime church. Omission of irregular members from the interviews left out those religious participants least likely to benefit from the teachings and discipline of the Santo Daime church.

d. Interviewers and subjects who had full knowledge of Ayahuasca use and of the implications of the interview responses were at high risk for interjecting their personal views into what should have been an objective scientific assessment. The likelihood of erroneous evaluations was increased by Dr. Halpern's strong prior advocacy for a right to use ayahuasca and the church members' understanding that these interviews would be the basis of a public record.

e. The absence of before-and-after measurements makes it uncertain that the group differences from "national norms" seen in the ayahuasca users actually represent any change from their pre-use status.

f. Small numbers of study subjects led to unreliable group estimates and an inability to detect infrequent serious reactions.

22. The defects enumerated above are cumulative, and they render the small interview study on which Dr. Halpern bases his conclusion insufficient to make any declaration of safety. The defects are so widespread and so serious as to place Dr. Halpern's research outside of the norms of accepted scientific conduct in the assessment of the safety of a substance for human consumption.

C. The Declarations and Studies of Dr. Charles S. Grob

23. Dr. Halpern's research and overall conclusion rely heavily on Dr. Grob's earlier work. The studies of the effects of ayahuasca relied upon by Dr. Grob possessed almost none of the desirable features outlined in the Principles section, above. In these studies, 15 male volunteers who had been members of the oldest parish of the syncretic

church União do Vegetal (UDV) for at least ten years underwent a series of psychological tests and one laboratory study, the results of which were compared to the results of the same procedures in 15 men of similar age, marital status and education. The UDV subjects had regularly consumed ayahuasca tea as a part of their engagement with UDV. None of the comparison subjects had drunk ayahuasca. In almost every respect measured, the UDV adherents exhibited more positive and fewer negative psychosocial qualities than did the comparison subjects. The one laboratory study indicated an alteration in the blood that pointed to a change in the density of chemical receptors on blood platelet cells in ayahuasca-consuming persons, with uncertain implications. In the taxonomy described above, this research was something like a retrospective comparative cohort study, with the important difference that the subjects were selected on the basis of their current characteristics (currently long-term members of the UDV or not) and not solely on the basis of their characteristics at some point in the past.

24. The research falls short of providing evidence on the health effects of ayahuasca for a number of reasons. First, the study groups were not comparable. According to Dr. Grob and his coinvestigators, UDV adherents abstain from alcohol and other intoxicating substances, they maintain high standards of responsibility to family and society, they are diligent and they are respectful of their church's leadership. In selecting long-term members of the UDV as their ayahuasca-exposed study group, Dr. Grob's Hoasca Project team included only persons who were able to conform to the church's precepts over extended periods that coincided with the use of ayahuasca. There was no similar requirement for stable, long-term willing church affiliation in the comparison group. By itself, this omission ensured the ayahuasca-consuming group

would be more likely to have a favorable psychological profile. The choice of compared subjects in such a way as to systematically affect the study outcome is called "selection bias." Selection bias would have rendered the study results uninterpretable, even if every other facet of the research had been flawless, which was not the case.

25. The selection of study subjects on the basis of current characteristics (in the Grob study, membership in the UDV) adds to the selection bias. In an extreme and hypothetical case, no one who had died as the direct or indirect result of ayahuasca use could have entered the study, and so the research was incapable of detecting lethal effects. The less extreme possibility that ayahuasca use could sometimes lead to behaviors incompatible with the UDV's standards of conduct is also undetectable in a study such as the one performed by the Hoasca Project. The reported study could not, even in principle, detect such serious problems. Such being the case, it is impossible to draw reassurance from the study.

26. The measurements in the study were incomplete. Investigators who wish to assess the effects of ayahuasca use would at a minimum need to have an assessment both before and after regular use of ayahuasca. The absence of any study-subject assessment that precedes regular ayahuasca use greatly compounds the uncertainties introduced by the selection procedures, as discussed above.

27. Because the investigators were aware of which subjects used ayahuasca and which did not, they may not have gathered health information in a comparable fashion in the two groups. I am not suggesting that the Hoasca Project team would have intentionally skewed information. The health assessor may be entirely unaware of biases

that arise from the differential expectations that arise when there is knowledge of exposure, and the study design that they chose left them open to the resulting error.

28. In common with almost all observational studies of drug effects, this research included subjects who were themselves aware of their exposure to the substance under study. This knowledge, coupled with beliefs and expectations inculcated and introduced by the UDV, could reasonably have affected the subjects' responses. Although the research tools involved standardized questionnaires and interview techniques, it is possible that the expectations of the researchers could have colored the interview, the test responses and their interpretation, and it is very likely that the beliefs and hopes of the study subjects could have done so. This concern does not apply to the single blood study, which is less susceptible to distortions arising from the investigators' and the subjects' knowledge of the subjects' use of ayahuasca.

29. For the reasons given in the preceding two paragraphs, the Hoasca Project's research benefited from neither of the advantages of "double-blind" research described in Paragraph 11 above. Interviewers with knowledge of the subjects' use of Ayahuasca and subjects with such knowledge providing responses are both at great risk of interjecting their preexisting subjective assessments into what ought to be an objective measurement process. These deficiencies in data collection procedure can be expected to systematically distort the results of the research, making it unreliable.

30. The number of study subjects was very small. With 15 subjects in each arm of the psychological testing comparison and even fewer for the blood study, the results are statistically unreliable. In measuring group averages for characteristics that may vary

between individuals, it is necessary to obtain large enough numbers of participants to get a statistically stable estimate of the average characteristics of each group.

31. Where only 15 subjects have been observed, there is also substantial room for having missed unacceptably common serious adverse consequences. To illustrate, if on the average one person in six developed serious consequences of ayahuasca use, it is possible to calculate by application of the binomial theorem that there is a greater than six percent chance that no cases at all might be seen in a particular group of 15, just by the luck of the draw. By the usual scientific standards of 95 percent confidence, observation of safety in 15 therefore does not rule out risks as high as one in six. The same mathematics is part of the reasons why trials of pharmaceutical products typically involve hundreds or thousands of study subjects.

32. The shortcomings that result from small numbers further reduce the reliability of the UDV studies for making any declaration of safety about the use of ayahuasca.

33. As a result of the basic deficiencies enumerated above, it is not possible to draw useful conclusions about the health effects of ayahuasca from the studies of UDV church members carried and relied upon by Dr. Grob.

34. An earlier publication by Dr. Grob provides evidence for a potentially serious potentiation of a prescription drug effect in a person participating in ritual consumption of Ayahuasca. In 1998 with James C. Callaway, Dr. Grob offered a case report of a 36 year old man under treatment for mild depression with fluoxetine (Prozac) who took ayahuasca, as follows:

“One hour after ingesting approximately 100 ml. of Ayahuasca, J.M. began to experience tremors, sweating, shivering and confusion. As his symptoms rapidly intensified, he staggered out of the religious ceremony and collapsed on the ground outside. For the next three hours J.M. reported that he continued to sweat profusely, display gross motor tremors and experience severe nausea and vomiting ... Although J.M. reports having been physically incapacitated for several hours and having received no treatment, he rapidly became asymptomatic after the four-hour post-ayahuasca ingestion point. There were no apparent long-term adverse sequelae.”

Anecdotal reports such as this are considered not as scientific proof of any relation, but rather as indicative of areas of concern that require further study. Nonetheless, in the conclusion of the case report, and in his declarations, Dr. Grob finds that this case represents a likely pharmacological interaction between ayahuasca and fluoxetine. Dr. Grob describes how he and his colleagues urged the UDV church not to give ayahuasca to members who were also taking drugs of the class to which fluoxetine belongs.

35. In sum, Dr. Grob’s research – which he himself characterized only as “preliminary” – suffered from a multitude of scientific flaws, all of which Dr. Halpern was to replicate, and add to, a decade later. Dr. Grob’s work cannot be relied upon to establish or even indicate the safety of ayahuasca. Dr. Grob’s anecdotal report of a toxic interaction between fluoxetine and ayahuasca is worrisome, and was sufficiently persuasive that the doctor and his colleagues took action to prevent further occurrences.

D. Robert S. Gable

36. Dr. Gable in 2007 published a summary of reported human studies of principal active ingredients of ayahuasca. He includes small number of citations to actual use of the tea. One is Dr. Halpern's report of a possible toxic interaction between ayahuasca and fluoxetine.

37. More worrisome in Gable's report is a report of psychotic incidents in UDV members.

“Over a period of 5 years, the medical studies section of the UDV documented between 13 and 24 cases in which ayahuasca might have been a contributing factor in a psychotic incident ([13], p. 701). The incidents documented by the UDV occurred from an estimated total of 25,000 servings of the hoasca tea.”

Gable goes on to make a flawed calculation with these figures, from which he draws incorrect reassurance about the safety of ayahuasca. The prevalence of “psychosis or schizophrenia” among adults in the United States is 1.3 percent. Prevalence is the fraction of a population possessing a characteristic. Noting that the number of psychotic incidents (between 13 and 24) is much less than 1.3 percent of 25,000, Gable concludes that there is no evidence that tea consumption increases the risk of psychosis. However, 25,000 administrations of tea over five years to persons who customarily take the tea almost weekly requires only a few hundred subjects. For example if 200 persons took the tea on an average of 25 times per year for five years, there would be 200 times 25 times 5 or 25,000 uses. A true prevalence of psychosis of 1.3 percent in 200 persons would give an expectation of only two or three cases. Against this backdrop, 13 to 24 persons with psychotic events may mean that there is a substantially elevated risk. The risk is even

more dramatic if there has been any screening to remove people with overt prior psychosis from entering the church. I do not believe that the case reports are consistent with safety of ayahuasca nor do I find that the population calculation that Gable reports supports his conclusion that “the risk of sustained psychological disturbance [is] minimal.”

E. Declaration of Nicholas V. Cozzi, PhD

38. Dr. Cozzi relies in part on the results from the Hoasca Project, which I have reviewed above, and found to be seriously deficient as the basis for any statement concerning the safety of ayahuasca, and which even Dr. Grob characterized as “preliminary.” Dr. Cozzi states:

“In fact, in a study conducted in the Brazilian Amazon in which Daime users were compared to matched controls, the Daime users revealed a high functional status with no evidence of personality or cognitive deterioration (Human Psychopharmacology Of Hoasca, A Plant Hallucinogen Used In Ritual Context In Brazil. CS Grob; DJ McKenna; JC Callaway; GS Brito; ES Neves; G Oberlaender; OL Saide; E Labigalini; C Tacla; CT Miranda; Strassman; KB Boone. *J. Nerv. Ment. Dis.*, 184, 86-94 [1996])”.

Dr. Cozzi makes this assertion, which is literally true, but which is also entirely misleading about reasonable conclusions from the study, without any further analysis or commentary. To the extent that this reliance informs his opinion, I believe that Dr. Cozzi is wrong.

Conclusions

39. The 2008 study performed by Dr. Halpern is without scientific merit and does not meet the norms of practice for medical research. Dr. Halpern's opinion cannot be relied upon.

40. The 1996 study by Dr. Grob, admittedly preliminary, suffers from many errors in conception and conduct and cannot be relied upon for statements about the safety of ayahuasca. Dr. Grob's report of an apparent toxic interaction between plant-derived substances and a pharmaceutical in a man taking fluoxetine (Prozac) who engaged in ritual use of ayahuasca is worrisome, as recognized by Dr. Grob.

41. The 2008 review by Mr. Gable contains an incorrect analysis of the risk of psychotic event in ayahuasca users, which leads him incorrectly to draw reassurance about the safety of ayahuasca. In fact, the data he cites point to an important elevation in the risk of psychosis associated with the ritual use of the tea.

42. Dr. Cozzi's declaration uncritically relies on demonstrably flawed work.

43. In my opinion, there is no evidence demonstrative of the safety of ayahuasca, and a strong possibility of elevated psychiatric risks and risks of toxic interactions with some prescribed medications.

44. Pursuant to 28 U.S.C. section 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: December 4, 2008



Alexander M. Walker, MD, DrPH